

(c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f), and (g) of Section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to same person.

MPEP § 706.02(k) provides in pertinent part:

Effective *November 29, 1999*, subject matter which was prior art under former 35 U.S.C. § 103 via 35 U.S.C. § 102(e) is now disqualified as prior art against the claimed invention if that subject matter and the claimed invention “were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.” This change to 35 U.S.C. 103(c) applies to all utility...applications filed after *November 29, 1999*, including continuing applications filed under 37 CFR 1.53(b)... *Emphasis Added.*

The two references are assigned on their face to Baxter International. The instant application is assigned to Baxter International. Further, the instant application is a continuation application that was filed on September 29, 2000. Thus, the changes to 35 U.S.C. § 103(c) as discussed above clearly apply to examination of the instant application. Therefore, the two references do not constitute applicable prior art under 35 U.S.C. § 103 to the above-identified patent application.

Accordingly, the rejections under 35 U.S.C. § 103 are improper as a matter of law and fact and Applicants respectfully request that they be withdrawn.

Claims 28-30, 32, 34, 36 and 38-51 have been rejected under 35 U.S.C. § 112. More specifically, Claims 28-30, 32, 34, 36 and 38-51 have been rejected under 35 U.S.C. § 112, second paragraph; and 28-30, 32, 34, 36, 38 and 39 have been rejected under 35 U.S.C. § 112, first paragraph. With respect to the rejection under 35 U.S.C. § 112, second paragraph, the Patent Office asserts that the claim terms “body fluid,” “at least one port extending from the container” and “controlled access” are allegedly unclear in scope and meaning.

With respect to the claim term “body fluid,” it is clear that as used in the art, the term “body fluid” can be used as Applicants’ have used same in their patent application. Furthermore, one of the basic tenants of patent law is that an applicant can define terms that are used in the

specification. Clearly, the term "body fluid" has been defined in the specification. As disclosed, the term "body fluid not only includes blood and its components, but also includes other fluids contained in the body such as blood components, leukocytes, red blood cells, white blood cells, plasma, etc. bone marrow, semen, or fluid containing structures, such as internal organs." See, Specification, page 8, lines 5-11.

The definition is not contrary to the prior art. Indeed, Applicants have pointed out where patents have issued in the same art unit that is examining the instant application including the term "body fluid" as used by Applicants. Moreover, the Oxford Dictionary of Science defines "body fluid" similar to Applicants' definition. Therefore, Applicants respectfully submit that the term "body fluid" as used by Applicants in their claims is not indefinite and does comply with the mandates of 35 U.S.C. § 112.

With respect to the terms "at least one port extending from the container" and "controlled access," Applicants believe that these terms are clear in meaning in scope. As disclosed, the container 10 includes ports 12 and 14 extending therefrom to provide access to an interior of the container. See, Specification, page 10, lines 1-4; Fig. 2. Further, the fluid flow can be controlled through the port(s) to provide a controlled access via a breakable cannula or the like as fully supported in the Specification on page 11 at lines 21-24. Therefore, Applicants believe that these claim terms do not render the claims indefinite and thus comply with 35 U.S.C. § 112.

The Patent Office has also objected to the use of the word "sealed" as modifying container in Claims 28-30, 32, 34, 36, 38 and 39 as adding new matter. Indeed, the container of the claimed invention can be a container such as used in the Optipat system that is disclosed in U.S. Patent No. 4,608,178 as set forth in Applicants' patent application. Clearly, that patent discloses "sealed containers." Furthermore, Applicants' patent application states that the container can be containers for housing blood and blood components available from the Fenwal Division of Baxter International. Such containers clearly must be sealed otherwise they could not "contain" any fluid. Moreover, Figure 2 clearly illustrates a sealed container otherwise the container walls would be flat, without any component contained within the interior contrary to the Patent Office's position.

Again, Applicants respectfully submit that the Patent Office is using an incorrect interpretation of the law. Nowhere does the law require that every word that is used in the claim must be present verbatim in the specification in order to provide support, meet the written

description requirement, or not add new matter. It is axiomatic that subject matter can be incorporated by reference. Further, it is axiomatic that subject matter can be provided by the drawings. The drawings clearly illustrate a sealed container. Applicants have incorporated by reference a patent that illustrates sealed containers. Additionally, Applicants have noted a commercially-available products that are sealed. Therefore, the Patent Office's rejection under 35 U.S.C. § 112 with respect to the term "sealed" is clearly not proper.

Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. § 112 be withdrawn.

Claims 40-42, 44, 45 and 49 stand rejected under 35 U.S.C. § 102(e) as being anticipated in view of the '107 *Patent* or the '629 *Patent*. Of the pending claims, Claim 40 is the sole independent claim. Claim 40 relates to a method for inactivating viruses in a body fluid. The method includes the steps of initially storing an amount of methylene blue in a container that includes an interior and at least one port extending from the container that provides controlled access to the interior wherein the container is constructed of a plastic material and includes an inner surface made of a non-polyvinyl chloride, plastic material; forming a mixture by adding at least a portion of the amount of the methylene blue to an amount of the body fluid, by use of the port, wherein the portion of methylene blue is a virucidally effective amount of the methylene blue and further wherein the mixture formed is within either the container or in a second container that initially housed the body fluid; and irradiating the mixture with a light field of a suitable intensity and wavelength for activating the methylene blue for a time sufficient to inactivate viruses in the mixture, while maintaining the mixture under a substantially no flow condition within the container in which the mixture is formed.

Applicants believe that the cited art fails to disclose a number of features of the claimed invention. For example, nowhere does the cited art disclose or arguably suggest a port extending from a container that provides controlled access to an interior of the container through which a mixture of the methylene blue and the body fluid can be formed. Indeed, the Patent Office merely suggests the cited art purportedly disclose that the container has an opening with a hose connected thereto. Based on at least these differences, Applicants believe that the cited art fails to anticipate Claims 40-42, 44, 45 and 49.


Accordingly, Applicants respectfully request that the anticipation rejection be withdrawn.

As previously discussed, Claims 28, 30, 32, 34, 38-47, 49 and 51 have been rejected under the judicially-created doctrine of obviousness type double patenting in view of the '107 *Patent*. In response, Applicants note that they will file a Terminal Disclaimer upon notice of allowable subject matter in this application.

For the foregoing reasons, Applicants respectfully request reconsideration of their patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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